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EXAMINER

GECKLE, C

SHERIDAN, ROSS & MC INTOSH
ONE UNITED BANK CTR., THIRTY-FIFTH FL.
1700 LINCOLN ST.
DENVER, CO 80203

ART UNIT	PAPER NUMBER
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188

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DATE MAILED:

07/30/91

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

- ☒ This application has been examined ☒ Responsive to communication filed on 5/23/91 ☒ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), 0 days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

- | | |
|---|--|
| 1. <input type="checkbox"/> Notice of References Cited by Examiner, PTO-892. | 2. <input type="checkbox"/> Notice re Patent Drawing, PTO-948. |
| 3. <input checked="" type="checkbox"/> Notice of Art Cited by Applicant, PTO-1449. | 4. <input type="checkbox"/> Notice of Informal Patent Application, Form PTO-152. |
| 5. <input type="checkbox"/> Information on How to Effect Drawing Changes, PTO-1474. | 6. <input type="checkbox"/> |

Part II SUMMARY OF ACTION

1. ☒ Claims ~~1-4~~ 1-4 and 6-64 are pending in the application.
Of the above, claims 9-52 are withdrawn from consideration.
2. ☒ Claims 5 has have been cancelled.
3. ☐ Claims are allowed.
4. ☒ Claims 1-4 and 6-8 and 53-64 are rejected.
5. ☐ Claims are objected to.
6. ☐ Claims are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable. ☐ not acceptable (see explanation or Notice re Patent Drawing, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____, has (have) been ☐ approved by the examiner. ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed on _____, has been ☐ approved. ☐ disapproved (see explanation).
12. ☐ Acknowledgment is made of the claim for priority under U.S.C. 119. The certified copy has ☐ been received ☐ not been received
☐ been filed in parent application, serial no. _____; filed on _____.
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

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Applicant's election of with traverse of Group I, claims 1-8 and 10 in Paper no. 8 is acknowledged. Since Applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the requirement is deemed to be proper by the Examiner and is therefore made FINAL. It should be noted that due to the amendment made to claim 10, the claim is hereby withdrawn from consideration as it pertains to a non-elected invention.

The disclosure is objected to because of the following informalities: claim 8 is improperly amended. The Applicant has not used the proper procedure for amending claims containing taxonomic nomenclature as disclosed on M.P.E.P. 714.22 or 37C.F.R. 1.121(d). The applicant must rewrite the entire claim and enter it with a new number as well as cancel the original claim to which the ~~new~~ claim is based. The rewritten claim would contain the proper underlines as they would appear in a printed patent. The use of double underlines in amended claims is not proper. Appropriate correction is required.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. § 112,

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first paragraph, as the specification, as originally filed, does not provide support for the invention as is now claimed.

There is no support for the a number of the changes made to the specification in the amendment of 5/23/91 (paper no. 8). The following changes are objected to as they appear to be the introduction of new matter into the specification: on page 16, line 8, the deletion of "10%" and insertion of "15%"; on page 33, lines 2 and 7, the deletion of "C22:5W3" and the insertion of "C22:6W3"; on page 54, line 36, the deletion of "39.0%" and the insertion of "29.0%"; on page 55, line 2, the deletion of "25.6%" and the insertion of "15.6%"; on page 62, line 21, after "supplement", the insertion of "(concentrations normalized to a 5,000 mg fatty acid egg)"; in claim 4, the insertion of "added to a fermentation medium prior to harvesting"; the addition of claim 53 in regards to the recitation of "to manipulate the resistance of the omega-3 highly unsaturated fatty acids to oxidation"; the addition in claims 54, 55, 58 and 59 in regards to the recitations of "sodium concentration up to about 6.58 g/l" and "sodium concentration up to about 4.61 g/l"; in claims 56 and 62, the recitation of "a fatty acid content of greater than about 6.7 percent of total cell dry weight"; and the substitution of figure 6.

It should also be noted Applicant cannot incorporate material by reference into the specification through a declaration.

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Claims 4, 53-56 and 58-64 are rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the objection to the specification.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as failing to provide an enabling disclosure.

At least some of the claims require one of ordinary skill in the art to have access to specific microbial strains. The specification indicates that deposits of these strains have been provided to the ATCC. It is not clear, however, whether or not the strains meet the criteria of M.P.E.P. 608.01(p)(c). Assurance must be provided to the effect that: (1) access to the cultures will be made available to the Commissioner to be entitled thereto under 37C.F.R. 1.14 and 35U.S.C. 122; (2) any restrictions on availability of the deposits to the public will be irrevocably removed upon the granting of a patent; and, (3) the deposits will be made "permanent." Maintenance of a deposit for a time period of 30 years from the date of deposit or 5 years after the last request whichever is longer, has been accepted as the equivalent of "permanent." Maintenance includes replacement of the cultures with equivalent cultures should those held on deposit become non-viable or detrimentally mutate. Assurance may be provided in the form of an affidavit, declaration, or averment under oath.

Claims 57, 61 and 64 are rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the objection to the specification.

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Claims 56 and 62-64 are rejected under 35 U.S.C. § 112, first paragraph, as the disclosure is enabling only for claims limited to only the particular strains disclosed to possess a omega-3 highly unsaturated fatty acid content of greater than 6.7% total cell dry weight. See M.P.E.P. §§ 706.03(n) and 706.03(z).

The specification has failed to enable any and all microorganisms of the order Thraustochytriales or any and all strains of the genera Thraustochytrium or Schizochytrium which possess the claimed omega-3 highly unsaturated fatty acid content. It would require undue experimentation on the part of the ordinary artisan to determine the genera, species and to a much greater extent, the strains which are encompassed by the claimed invention.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4, 6-8 and 55-64 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, the recitation of "a source of omega-3 highly

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unsaturated fatty acids comprising microorganisms" is vague and indefinite. It is unclear what is meant by the recitation as the use of the open terminology "comprising" renders the metes and bounds of the claim indeterminable.

Claim 7 is vague and indefinite in its recitation as it is not clear how the manipulation of bioavailability of omega-3 highly unsaturated fatty acids in a microorganism is accomplished and if such manipulation encompasses an extraction procedure.

Claim 8 is vague and indefinite as there is no antecedent basis for the recitation "said group."

In claim 53, the recitation of "to manipulate the resistance of the omega-3 highly unsaturated fatty acids to oxidation" is vague and indefinite. It is unclear what is meant by the phrase as it defines the claim as the specification fails to set forth parameters, elements or conditions which define such a manipulation.

Claims 54 and 55 lack antecedent basis in the previous claim. The previous claim does not provide for a culturing step. It is drawn to a food product. Further, it is not clear what is meant by the claims in terms of whether or not it is the food composition that is being fermented or merely the microorganism.

Claim 59 is vague and indefinite as it does not appear to further limit the claim upon which it depends. The claim is encompassed by claim 58.

Claims 57, 61 and 64 are vague and indefinite in their

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recitations of "wherein said microorganisms are selected from the group consisting of microorganisms identified by ATCC Accession Numbers 20888, 20889, 20890, 20891, 20892, mutant strains derived therefrom, and mixtures thereof." It is preferable to identify the strains by genus or species names as well as by accession number. It is not clear what is meant by "mutant strains derived therefrom" as it is not clear what is being referred to insofar as a parent strain is concerned.

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 1-3, 8 and 54-64 are rejected under 35 U.S.C. § 103 as being unpatentable over Long.

The claimed invention is drawn to a food product composition which comprises a source of omega-3 highly unsaturated fatty acids from microorganisms of the order Thraustochytriales, more specifically from the genera Thraustochytrium and Schizochytrium.

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Long teaches the production of omega-3 fatty acids by heterotrophic microorganisms from the genera Thraustochytrium and Schizochytrium. Long also discloses the omega-3 fatty acids to be useful in nutrition as a nutritional additive to human diets as well as an animal feed additive. Long teaches the genera as a source of omega-3 highly unsaturated fatty acids (HUFA). The choice of the form of the omega-3 highly unsaturated fatty acids (HUFA) in terms of whether the whole microorganism is used or whether it is extracted would have been a matter of judicious selection on the part of the ordinary artisan. Optimization of parameters such as culturing conditions for the microorganisms to be added to the food product is well within the purview of the ordinary artisan absent unexpected results.

Applicant argue that the claims are distinguished from Long as the source is in the form of whole cells and not extracted as taught Long, the microorganisms are cultured in low salinity, and the content of the omega-3 HUFA is higher in the microorganisms of the claimed invention than those disclosed in Long.

Applicant's comments concerning extraction of the omega-3 HUFA versus use of the whole cells containing omega-3 HUFA is not found persuasive. Applicant has not demonstrated any difference between the two forms other than what one of ordinary skill would have expected. Long chose to separate out the undesired or extraneous material from the fatty acids of interest. Applicant's choice not to extract does not distract from the fact

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that the reference teaches the same source of the fatty acids as is claimed and further teaches this source in food. No unexpected results are shown in using whole cells versus the extract.

Applicants alleged criticality based on the new matter inserted into the claims is not found persuasive. The culturing conditions of the microorganisms in terms of determining the salinity of the medium is considered routine optimization of parameters. In regards to the arguments concerning the omega-3 HUFA content in the cells, the claimed invention has not been so limited in all cases.

Claims 4,6,7 and 53 are rejected under 35 U.S.C. § 103 as being unpatentable over Long as applied to claims 1-3, 8, 54-64 above, and further in view of Chang et al. and Traitler et al.

The instant claims are rejected for reasons of record as stated on pages 6 and 7 of the last Office action.

Applicant traverses on the grounds that the antioxidant is added to whole cells prior to extrusion process and that the Traitler et al. reference teaches a different reason for extrusion than that of the claimed invention.

The alleged criticality of the addition of an antioxidant to whole cells prior to extrusion appears to be unsupported in the specification is not found persuasive. Support of such criticality has not been established or demonstrated by a showing of evidence. Applicant urges that Traitler et al. teaches the

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use of antioxidants and extrusion in order to enhance extraction of fatty acids from seeds while the claimed invention teaches extrusion in order to manipulate the bioavailability of the omega-3 HUFA. It is maintained that both appear to be concerned with enhancement of recovery of fatty acids. Extrusion processes and the use of antioxidants for improving stability have been well established in the art as evidence by the teachings of the prior art of record.

Claims 1-3, 8, 54-64 are rejected under 35 U.S.C. § 103 as being unpatentable over Ellenbogen et al. taken with Kyle.

The instant claims are rejected for reasons of record as stated on page 8 of the last Office action.

Applicant traverses on the grounds that the Ellenbogen et al. reference studied the production of omega-3 fatty acids in Thraustochytrium and Schizochytrium for a different purpose and therefore "the potential of an organism for use in the production of fatty acids cannot be evaluated." Applicant urges that the reference fails to render obvious the whole cell microorganism of the claimed order Thraustochytriales as a source of omega-3 HUFA in food.

The Ellenbogen et al. reference is not relied upon alone to support a prima facie case of obviousness. It is relied upon to teach the genera claimed possess the capability of producing omega-3 highly unsaturated fatty acids. Kyle is relied upon for the motivation to screen, select, and improve the yield of such

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fatty acids in microalgal species. Applicant's arguments in regard to Kyle teaching away from the claimed invention are not found persuasive as such parameters discussed are not found in the claims.

Claims 4,6-7 and 53 are rejected under 35 U.S.C. § 103 as being unpatentable over Ellenbogen et al. taken with Kyle as applied to claims 1-3, 8, 54-64 above, and further in view of Chang et al. and Traitler et al.

The instant claims are rejected for reasons of record as stated on page 8 and 9 of the last Office action.

Applicant traverses on the grounds that it is not obvious to combine the references. Applicant argues further that the references teach away from the claimed invention as the claimed invention teaches the use of "preferably whole cell microorganisms" for advantages such as prevention of oxidation.

The art is considered to be analogous art by the Examiner and the combination is deemed proper. Chang et al. and Traitler et al. deal with antioxidants and extrusion processes involving fatty acids susceptible to degradation. One of ordinary skill in the art would have found the teachings in these references pertinent when involved in products or processes dealing with omega-3 highly unsaturated fatty acids. Applicant's arguments concerning the whole microorganisms versus extraction has been addressed previously and has not been found persuasive. Applicant's allegation that since the "whole cell microorganism

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already has a high omega-3 HUFA content, the omega-3 HUFAs do not need to be extracted" is not supported by evidence and certainly such limitations are not encompassed by all the claims.

No claim is allowed.

Applicant's amendment necessitated the new grounds of rejection. Accordingly, THIS ACTION IS MADE FINAL. See M.P.E.P. § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a). The practice of automatically extending the shortened statutory period an additional month upon the filing of a timely first response to a final rejection has been discontinued by the Office. See 1021 TMOG 35.

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

Any inquiry concerning this communication should be directed to Carol Geckle at telephone number (703) 308-0196.


DOUGLAS W. ROBINSON
SUPERVISORY PATENT EXAMINER
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